

Bio- and Nanomedical Commercialization: Concept to Market

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COURSE OVERVIEW

This course offers a comprehensive overview of key elements involved in entrepreneurship and commercialization of biomedical and nanomedicine products. Business models, protection of intellectual property, and business valuation will be discussed. This course also covers regulatory processes, as well as mechanisms for raising capital to support R&D. To apply concepts learned throughout the course, students will work as a team to develop a small business proposal that will be pitched in front of investors and entrepreneurs. Proposal topics may be selected from key areas in nanomedicine and/or biotechnology, as well as ongoing research activities at Northeastern University and other leading research centers.

This is one of four courses offered through the Nanomedicine Academy, a joint partnership between Northeastern University, Morgan State University, University of Puerto Rico Mayaguez, Tuskegee University, and Florida International University supported by the National Science Foundation (NSF). This course will be lead by instructors at Northeastern University and will feature rotating talks by guest experts.

Guiding Questions

- How do entrepreneurs develop a product concept that addresses a real market need?
- What are the key elements to a successful business plan?
- How are start-ups organized and managed?
- What is the regulatory pathway for clinical products? How does this impact corporate R&D pipeline and financials?

Outcomes and Objectives

- Identify the key steps and bottlenecks for the commercialization of nanomedicine drugs and devices
- Objectively evaluate potential opportunities for innovation, entrepreneurship, and value-extraction
- Describe high- potential, technology-intensive, commercial opportunities in markets of interest

TEXTBOOKS AND REFERENCES

There is no textbook because this course draws widely from peer-reviewed literature and investigates cutting-edge work in the field of nanomedicine. Weekly reading materials will be provided within Blackboard. Additionally, you will be asked to search library resources and the web as part of your assignments.

HOW THE COURSE IS STRUCTURED

This course features a variety of interactive classroom and online activities that will allow you to engage with classmates and faculty at multiple institutions. These include:

Interactive Web Lectures: You will attend live lectures led by Nanomedicine Academy faculty and guest experts via web conferencing hosted in your classroom on Wednesdays. Please note that attendance of these lectures is **mandatory** and all absences must be excused *in advance*. **We will be featuring high-profile guest speakers each week starting promptly at 4pm, so please arrive on time!** Your participation in Q&A is worth 15% of your grade.

Team Business Proposal and Presentation: Over the course of the semester, you will create a small business proposal. Each week, you will be working as a team to develop a different component of your small business plan. You will receive feedback from the course instructors, therefore it will be important to complete the assignments in a timely manner, but then also go back and edit your work based on the instructor feedback. By the end of the semester, you will have created an entire business plan and presentation that will be handed in for a grade. For group assignments, the entire group will receive same grade, regardless of who participated, so it is in your best interest to ensure as a group that high quality work is being handed in. The weekly assignments are worth 30% of your grade. The group presentation and business plan is 50% of your grade.

In-class Group Work Time: You will be provided with time in class to work as group and meet with the course instructors (either face-to-face or via web conferencing). **All students are required to stay and work during this time.** You are encouraged to bring laptops or other web-enabled devices for this time, but please be sure to put them away during the seminars and lectures. Your participation in in-class activities is worth 5% of your grade.

GUEST LECTURES

Successful entrepreneurs, local and regional leaders, venture capitalists, regulatory officials, all with expertise in relevant subjects, are invited to cover segments of this course. Guest lectures hosted by this course in 2016 included:

- **Pathways to a career in venture capital**
Christopher de Souza, PhD, Broadview Ventures
- **Healthcare Innovation: Balancing Creativity with Skepticism**
Andrew Miller, Vice President & Venture Partner, PureTech
- **Nanomedicine Today: Achievements and Challenges**
Lajos Balogh, Editor-in-Chief, Nanomedicine: Nanotechnology, Biology, and Medicine
- **Patenting Bio- & Nanotechnology: From Idea to Approval**
Joel Bresler and Andrew Curtin, Center for Research Innovation, NEU

- **Business School of Hard Knocks: An Entrepreneur's Perspective**
Peter Steiger, VP of Medical Imaging, PAREXEL Informatics
- **Academic Entrepreneurship: Lessons learned**
Ali Khademhosseini, Professor, Harvard Medical School
- **Cancer Nanomedicines: Promises and challenges**
Vahe Bedian, Director, Global Product and Portfolio Strategy at AstraZeneca
- **From quantum dots to nano-droplets: Commercializing life science tools & diagnostics**
Andy Watson, Vice President Corporate Development, Cell Signaling Technology (CST)
- **Commercialization of hemostatic agents: Progress and Challenges**
Terrence Norchi, MD, President and CEO of Arch Therapeutics

TIMELINE AND GRADING

Below is a list of topics that will be covered in this course. The order of topics may change based on the availability of guest speakers.

1/11 Week One: Nanomedicine global market: Current status and key challenges

1/18 Week Two: Key Elements from Concept to Market

1/25 Week Three: Business Options and Structures

2/1 Week Four: Sources of Capital and Dilution

2/8 Week Five: Medical Devices

2/15 Week Six: Business Plan design

2/22 Week Seven: Intellectual Property

3/1 Week Eight: Valuation

3/8 Week Nine: Spring Break (no class)

3/15 Week Ten: Regulatory processes

3/22 Week Eleven: Market entry, exit, and financial metrics

3/29 Week Twelve: Manufacturing, sales, and distribution

4/5 Week Thirteen: Role of management

4/12 Week Fourteen: Advanced topics

4/19 Week Fifteen: In-class group business plan presentations

You will be assessed on the basis of an individual and group writing assignments, a team business proposal, a group presentation, and active participation in class activities.

Assignment	Description	Due Date	Grade
Assignments	Individual and group writing assignments	Weekly	30%
Business Proposal	Team small business plan	Wed 4/12	30%
Team Presentation	In-class group business plan presentation with Q&A	Wed 4/19	20%
Participation	Participation in Q&A and regular in-class activities	Weekly	20%

COMMUNICATION WITH YOUR PEERS

The students who attend this course with you come from universities in 5 different states and territories across the U.S. Each of you brings a unique background, area of expertise, and perspective to the course. We are providing you with the opportunity to interact with each other in a variety of ways so that you can benefit from each other's experiences.

Course Blog: You will have several opportunities to post your work to a shared blog so that the entire class can benefit and learn from your research. You are also asked to provide a short biography and introduction so that the other class members can get to know you.

Group Assignments: You will be provided with all the software needed to perform group brainstorming sessions, prepare a small business proposal, and create a presentation. The great thing about all this online software means it is no longer necessary to be in same room all the time to do a group project! You are also encouraged to comment on the work of other groups!

Live Broadcast Group Presentation: You will each have the opportunity to pitch your business presentation in front of the entire multi-institutional student body on the last day of class.

"Burning Questions" Discussion Forum: As you attend lectures and work on your assignments, you might come across new topics on which you have questions. You are encouraged to post these questions in this discussion forum. The course instructors and TAs will work to see that all these questions are answered by the end of the semester, either in the course materials or discussion forum. You are also free to answer questions that pop up here! General questions about assignments can also be posted here. [Tip: The discussion "subscribe" option forwards messages directly to your email, making it easier to monitor.](#)

COMMUNICATION WITH THE INSTRUCTORS

Instructor Participation in the Discussion Forum, Course Blog, and Group Wikis: These sites within the Blackboard interface are intended to create a conversation among students, not a back-and-forth between the professor and students. We believe in your capacity for taking the discussion in interesting and productive directions. The course instructors will occasionally provide expert advice and personalized help to challenge and motivate you. Even though we may not respond to every thread, please know we are "listening" intently. Instructor feedback on assignments will be provided directly to the individual and/or group.

Messages and Announcements: We will post announcements with observations and questions designed to spur, focus, or deepen the whole group's discussion. We will also send logistical updates as needed. These announcements will typically be posted to a Blackboard announcement that is also forwarded to your email address. This redundancy ensures that everyone in the course sees the communication.

Face-time with a Course Instructor: As part of your weekly assignments, the course instructors will provide written or oral feedback. You will also be offered opportunities to communicate face-to-face with the course instructors (either in class or via web-conferencing) during the in-class work periods. Additionally, we have designated a local Faculty Facilitator at each institution. The role of this faculty is to host the classroom space, act as a local point of contact for any questions you have, and provide additional mentoring for group projects. We encourage you to seek the advice of your local Faculty Facilitator as you develop your business proposal.

Technical Questions and Concerns

Please visit Blackboard's Online Support Center at <http://nuonlinebbsupport.neu.edu> to access tutorials and live chat support, or call the Center at (855) 836-3520. **This 24/7 hotline is available to ALL nanomedicine students; no matter what institution you attend.**

Getting Help: The best place to go for help depends on the specifics of your concern or question. As noted above, please post *course-related questions and concerns* in the "Burning Questions" Discussion Forum on BB. It's also a good idea to check this discussion regularly to stay in the loop on questions and clarifications. **Tip:** The discussion "subscribe" option forwards messages directly to your email, making it easier to monitor.

COURSE POLICIES

1. Class attendance is mandatory. You are encouraged to also actively participate in this course by engaging local and remote instructors in discussion of course content and asking questions during lectures.
2. You are expected to check Blackboard regularly. All required assignments, readings, course communications, and lecture notes/presentations will be posted on Blackboard.
3. You are expected to follow guidelines stated in the NEU Academic Integrity Policy (<http://www.northeastern.edu/osccr/academichonesty.html>)
4. The use of mobile devices and laptops during lectures and guest talks is not allowed. You are encouraged to bring and use electronic devices during the in-class group work sessions.